

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D. 08 FEB 2005

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| Applicant's or agent's file reference P015153WO WJR | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416) | |
| International application No. PCT/GB 03/04651 | International filing date (day/month/year) 29.10.2003 | Priority date (day/month/year) 01.11.2002 | |
| International Patent Classification (IPC) or both national classification and IPC A61L2/00 | | | |
| Applicant MEDICAL RESEARCH COUNCIL et al. | | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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| Date of submission of the demand 19.05.2004 | Date of completion of this report 04.02.2005 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Jochheim, J Telephone No. +49 89 2399-8632 |



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/04651**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, Pages

1-23 as originally filed

Claims, Numbers

1-16 filed with telefax on 19.05.2004

Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-----------|
| Novelty (N) | Yes: Claims | |
| | No: Claims | 1-16: Yes |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-16: No |
| Industrial applicability (IA) | Yes: Claims | |
| | No: Claims | 1-16: Yes |

2. Citations and explanations

see separate sheet

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EXAMINATION REPORT - SEPARATE SHEET**

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Re Item V

Reasoned statement under **Article 35(2) PCT** with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents (D) are considered to be of relevance for the application; the numbering will be adhered to in the rest of the procedure:

- D1:** WO-A-01/54736 (SCOTT MICHAEL R ;UNIV CALIFORNIA (US); PRUSINER STANLEY B (US); SU) 2 August 2001 (2001-08-02)
- D2:** WO-A-01/35104 (COMMISSARIAT ENERGIE ATOMIQUE ;COMOY EMMANUEL (FR); GRASSI JACQUES) 17 May 2001 (2001-05-17)
- D3:** WO-A-02/083082 (BIORESOURCE INTERNATIONAL INC) 24 October 2002 (2002-10-24)
- D4:** FR-A-2 774 988 (COMMISSARIAT ENERGIE ATOMIQUE) 20 August 1999 (1999-08-20)
- D5:** WO-A-02/057789 (ENFER TECHNOLOGY LTD ;O'CONNOR MICHAEL (IE)) 25 July 2002 (2002-07-25)

(Not necessarily all documents are referred to in this communication, but may become of higher importance during the procedure. This does not exclude the possibility that also additional documents may be added to the list during the procedure.)

The following abbreviations in parentheses apply to this document: page (p), column (co), line (l), example (ex), claim (cl).

1. Article 33(2) PCT (Novelty)

- 1.1 Claim 1 meets the requirements of Article 33(2) PCT**, because the prior art does not disclose a method for prion decontamination comprising contacting an entity to be decontaminated with a detergent, with a first protease and with a second protease.
- 1.2 Claim 13 meets the requirements of Article 33(2) PCT**, because the prior art does not disclose a kit comprising a detergent and two or more proteases as defined in claim 13.
- 1.4 Claim 15 meets the requirements of Article 33(2) PCT**, because the prior art does not disclose a composition comprising a detergent and two or more

proteases as defined in claim 15.

2. Article 33(3) PCT (Inventive Step)

2.1 **Claim 1** differs from the closest state of the art (which is seen in **D1**, see in particular examples 17 and 18) in that an entity is treated with two proteases. The objective problem posed in view of what is known from **D1** would appear to be to provide an alternative method of prion decontamination.

The simple repetition of the treatment with a protease would not appear to be inventive. As the applicant states himself on p 4, l 28-29 of the present description, it "is plain to a person of ordinary skill in the art, the higher the concentration of protease(s), the greater and more rapid destruction is achieved". Without further evidence that the method of claim 6 solves a technical problem in a non-obvious manner, no inventive step can be acknowledged to the subject-matter of said claim.

2.2 For similar reasons as for claim 1, no inventive step can be acknowledged for claims 13 and 15.

2.3 The remaining dependent **claims 2-12, 14, and 16** do not fulfill the requirements of **Article 56 EPC** because their subject-matter is either known from **D1** or **D2** or **D3** or **D4** or **D5** or they merely represent a choice among obvious design possibilities from which a person skilled in the art would choose without use of inventive skill in order to arrive at the solution of the problem posed or they do not add any unexpected effect over what is known from the prior art.

3. Article 33(4) PCT (Industrial Applicability)

3.1 Industrial applicability is given, claims 1-16 meet the requirements of **Article 33(4) PCT**.

4. Further Remarks

4.1 The sequence of treatment in claim 1 and is not clear. Since it is indicated in the description that simultaneous treatment with SDS and protease may reduce the level of decontamination, such an indication would appear to be essential for the claim. Basis is to be found in example 2 of the present description.

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- 4.2 Further inconsistencies in the claims are that claims 1 and 13 merely refer to a detergent, whereas claim 15 calls for an ionic detergent. The reason for this is unclear.